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IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

Applicant:

Maryse Lafouasse

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Examiner:

David H. Kruse

For:

"INBRED MAIZE LINE PHOGC"

Assistant Commissioner for Patents Washington, D.C. 20231

> **RULE 132 DECLARATION** OF DR. STEPHEN SMITH

Sir:

- I, Stephen Smith, PhD., do hereby declare and say as follows:
- 1. I am skilled in the art of the field of the invention. I have a Ph.D. in Biochemical Systematics and Taxonomy of Maize and its Wild Relatives from Birmingham University. I have a M.Sc. in the Conservation and Utilization of Plant Genetic Resources from Birmingham University. I have a Bachelor of Science degree in Plant Sciences from London University. Since 1977 I have been engaged in the development, study and application of molecular markers to genetics, measuring genetic diversity and tracking pedigrees. I commenced this work at North Carolina State University as a post-doctoral research fellow. I have continued my engagement in these studies during my employment by Pioneer Hi-Bred from 1980 until the present. These studies have resulted in numerous scientific articles that have appeared in peer reviewed scientific literature.
- 2. This declaration is in response to the Examiner's rejection under, 35 U.S.C. § 102(e) as anticipated by or, in the alternative, under 35 U.S.C. § 103(a) as obvious over Rietmann (U.S. Patent No. 6,310,274).
- 3. I have conducted an analysis of SSR marker data for inbred PH0GC and the inbred cited as prior art, PH36E. Out of a total of 144 SSR loci examined, which allowed a sampling of each chromosome, there are 75 markers that show differences between PH0GC and PH36E. This represents a difference for 52% for the markers tested. Of

Appendix E



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these 75 markers, 31 were greater than 50 cm in distance, or unlinked on the genetic map.

- 4. Upon crossing PHOGC to any other malze line and selfing successive fillal generations, one would within the realm of what is statistically possible, obtain a progeny inbred maize line that retains genetic contribution from PH0GC. Assuming that (i) the cited prior art is used as the maize line to which PHOGC is crossed, (ii) that the only difference between PH0GC and PH36E are these 85 markers, and (iii) that all markers within a 50 cM distance will segregate together, then the odds of obtaining a PH0GC progeny inbred that is the same as PH36E after one cycle of breeding, is 1 in 231 or 1 in 2,147,483,648. Statistically it is extremely unlikely that a PH0GC progeny, after one cycle of breeding, would be the same as PH36E.
- Further, the assumptions made above vastly overstate the likelihood of breeding PH36E from PH0GC. For example, it is common practice in quantitative genetics to determine the relation of plants by differences in markers. In doing so, one extrapolates that a percentage difference in markers is indicative of a difference in the whole genome. To assume that the only differences between PH0GC and PH36E are for these 75 markers, when 75 markers constitute 52% of the 144 SSR loci examined, is a gross and unrealistic assumption. Further the current maize genetic map only has approximately sixty 50cM units, so by applying this limitation the maximum number of independently segregating loci one could obtain, using the most different maize lines that could ever be found, is sixty. These assumptions result in an over estimate of the odds of breeding PH36E from PH0GC.
- Given the difference in molecular markers between PH0GC and PH36E, it is my expert opinion that PH0GC and PH36E are very distinct inventions. It is also my expert opinion that, within the realm of what is statistically possible, any progeny of PHOGC developed through crossing PH0GC with another plant will be distinct from PH36E. Given the facts and based on my education and scientific experience, I believe that the invention as claimed is not obvious nor anticipated by Rietmann (U.S. Patent No. 6,310,274).
- 7. I hereby declare that all statements made herein of my own knowledge are true and that all statements made on information and belief are believed to be true; and further that these statements were made with the knowledge that willful false statements and the like are punishable by fine or imprisonment, or both, under Section 1001 of Title 18 of the United States Code and that such willful false statements may jeopardize the validity of the application or any patent issued thereon.

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Date: Mark 14 4 2003

By:

Stephen Smith